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| APPLICATION NO. | FILING DATE | FIRST NAMED INVENTOR | ATTORNEY DOCKET NO. | CONFIRMATION NO. |
|---|---|---|---|---|
| 09/986,945 | 11/13/2001 | Juan Mantelle | 041457-0633 | 6420 |

22428 7590 07/10/2008
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| EXAMINER | |
|---|---|
| EBRAHIM, NABILA G | |

| ART UNIT | PAPER NUMBER |
|---|---|
| 1618 | |

| MAIL DATE | DELIVERY MODE |
|---|---|
| 07/10/2008 | PAPER |

**Please find below and/or attached an Office communication concerning this application or proceeding.**

The time period for reply, if any, is set in the attached communication.

| Office Action Summary | Application No. | Applicant(s) | |
|---|---|---|---|
| | 09/986,945 | MANTELLE ET AL. | |
| | Examiner | Art Unit | |
| | NABILA G. EBRAHIM | 1618 | |

*-- The MAILING DATE of this communication appears on the cover sheet with the correspondence address --*

**Period for Reply**

A SHORTENED STATUTORY PERIOD FOR REPLY IS SET TO EXPIRE *3* MONTH(S) OR THIRTY (30) DAYS, WHICHEVER IS LONGER, FROM THE MAILING DATE OF THIS COMMUNICATION.

- Extensions of time may be available under the provisions of 37 CFR 1.136(a). In no event, however, may a reply be timely filed after SIX (6) MONTHS from the mailing date of this communication.
- If NO period for reply is specified above, the maximum statutory period will apply and will expire SIX (6) MONTHS from the mailing date of this communication.
- Failure to reply within the set or extended period for reply will, by statute, cause the application to become ABANDONED (35 U.S.C. § 133). Any reply received by the Office later than three months after the mailing date of this communication, even if timely filed, may reduce any earned patent term adjustment. See 37 CFR 1.704(b).

**Status**

1)☒ Responsive to communication(s) filed on *18 March 2008*.

2a)☒ This action is **FINAL**. 2b)☐ This action is non-final.

3)☐ Since this application is in condition for allowance except for formal matters, prosecution as to the merits is closed in accordance with the practice under *Ex parte Quayle*, 1935 C.D. 11, 453 O.G. 213.

**Disposition of Claims**

4)☒ Claim(s) *1-26* is/are pending in the application.

4a) Of the above claim(s) _____ is/are withdrawn from consideration.

5)☐ Claim(s) _____ is/are allowed.

6)☒ Claim(s) *1-26* is/are rejected.

7)☐ Claim(s) _____ is/are objected to.

8)☐ Claim(s) _____ are subject to restriction and/or election requirement.

**Application Papers**

9)☐ The specification is objected to by the Examiner.

10)☐ The drawing(s) filed on _____ is/are: a)☐ accepted or b)☐ objected to by the Examiner.

Applicant may not request that any objection to the drawing(s) be held in abeyance. See 37 CFR 1.85(a).

Replacement drawing sheet(s) including the correction is required if the drawing(s) is objected to. See 37 CFR 1.121(d).

11)☐ The oath or declaration is objected to by the Examiner. Note the attached Office Action or form PTO-152.

**Priority under 35 U.S.C. § 119**

12)☐ Acknowledgment is made of a claim for foreign priority under 35 U.S.C. § 119(a)-(d) or (f).

a)☐ All b)☐ Some * c)☐ None of:

1.☐ Certified copies of the priority documents have been received.

2.☐ Certified copies of the priority documents have been received in Application No. _____.

3.☐ Copies of the certified copies of the priority documents have been received in this National Stage application from the International Bureau (PCT Rule 17.2(a)).

* See the attached detailed Office action for a list of the certified copies not received.

**Attachment(s)**

1) ☐ Notice of References Cited (PTO-892)
2) ☐ Notice of Draftsperson's Patent Drawing Review (PTO-948)
3) ☐ Information Disclosure Statement(s) (PTO/SB/08) Paper No(s)/Mail Date _____.
4) ☐ Interview Summary (PTO-413) Paper No(s)/Mail Date. _____ .
5) ☐ Notice of Informal Patent Application
6) ☐ Other: _____.

## DETAILED ACTION

***Status of Claims:***

Claims 1-23 are pending in the application.

***Status of Office Action***: Final

### *Claim Rejections - 35 USC § 112*

1. The following is a quotation of the second paragraph of 35 U.S.C. 112:

> The specification shall conclude with one or more claims particularly pointing out and distinctly claiming the subject matter which the applicant regards as his invention.

a) Claim 1 and dependent claims are rejected under 35 U.S.C. 112, second paragraph, as being indefinite for failing to particularly point out and distinctly claim the subject matter which applicant regards as the invention. The claim recites "below processing temperatures" the phrase renders the claim unclear because neither the processing temperature nor the active agent is recited. Explanation is required.

*b)* Claims 1, 5 are rejected under 35 U.S.C. 112, second paragraph, as being indefinite for failing to particularly point out and distinctly claim the subject matter which applicant regards as the invention. The claims recite "equal to or greater than the normal boiling points of the at least one low molecular weight drug". The meaning is vague since the drug is not known; there is no way to compare its boiling point to the prior art.

### *Claim Rejections - 35 USC § 102*

2. The following is a quotation of the appropriate paragraphs of 35

U.S.C. 102 that form the basis for the rejections under this section made in this Office action:
A person shall be entitled to a patent unless

(b) the invention was patented or described in a printed publication in this or a foreign country or in public use or on sale in this country, more than one year prior to the date of application for patent in the United States.

a. Claims 1-6, and 10-21 remain rejected under 35 U.S.C. 102(b) as being anticipated by

Miranda Jesus et al. WO 9300058 (Miranda).

Miranda teaches transdermal drug delivery system and more particularly, to a transdermal drug delivery composition wherein a blend of polymers is utilized to affect the rate of drug delivery from the composition. The composition comprises a blend of polymers, and a therapeutically effective amount of a drug or more, which amount may reach between 5-40% by weight; this percentage is within the percentage recited in claim 6 (page 2). In a preferred embodiment of the improved pressure-sensitive adhesive, the first polymeric adhesive material is a polyacrylate and the second adhesive material is a polysiloxane (page 6). The shear resistant of the acrylic polymer in a preferred embodiment of the invention, the multiple polymer adhesive system comprises a blend of an acrylic shear-resistant pressure-sensitive adhesive and a silicone pressure-sensitive adhesive (page 5). Miranda discloses that the transdermal drug delivery device may include a backing material and a release liner as is known in the art (page 3). The drug comprised in the transdermal system may be nicotine (page 7), and the pressure-sensitive adhesive composition of the type, which is suitable as a matrix for controlled release of a bioactive agent (page 5). Miranda also suggests a free base, free acid drug (claim 34) and teaches that polyacrylate is preferably present in the pressure-sensitive adhesive composition in an amount ranging from about 2-96% by weight and the polysiloxane is present in an amount ranging from about 98-4%, and the composition according to Miranda comprises fillers, and excipients (page 6). The same steps of instant claim 17 are recited in (example 1) of Miranda who added the nitroglycerin was added as a solution in toluene mixed together with the polyacrylate.

The resulting composition had the ingredient concentrations on a "dry" basis, that is, after removal of volatile process solvents. Note that the molecular weight of nicotine is 162.23 g/mol which reads on the instant claims that require the molecular weight of the active agent is lower

that 300 dalton.

Because the same compounds have same properties, the recitation of "pressure-sensitive adhesive polymer having a shear resistance which is greater than or equal to 50 hours at 8 pounds per square inch and 720 Fahrenheit." Is an inherent property to the same compounds of the preparation disclosed by Miranda.

***Conclusion: claims 1-6, and 10-21 are anticipated by Miranda.***

> (e) the invention was described in a patent granted on an application for patent by another filed in the United States before the invention thereof by the applicant for patent, or on an international application by another who has fulfilled the requirements of paragraphs (1), (2), and (4) of section 371(c) of this title before the invention thereof by the applicant for patent.

The changes made to 35 U.S.C. 102(e) by the American Inventors Protection Act of 1999 (AIPA) and the Intellectual Property and High Technology Technical Amendments Act of 2002 do not apply when the reference is a U.S. patent resulting directly or indirectly from an international application filed before November 29, 2000. Therefore, the prior art date of the reference is determined under 35 U.S.C. 102(e) prior to the amendment by the AIPA (pre-AIPA 35 U.S.C. 102(e)).

b. Claims 1-5, 7, 8, 10, 12, 14-21 remain rejected under 35 U.S.C. 102(b) as being anticipated by Pfister et al EP0524776.

Pfister teaches a silicone pressure sensitive adhesive composition, which is compatible with drugs, excipients, co-solvents and skin penetration enhancers is disclosed which includes a cohesive strengthening agent. The adhesive is useful as a transdermal drug delivery device. A blend of polymers are used in the invention like siloxane polymers (page 3, line 10+), and acrylic acid polymers of high shear resistance that has molecular weights from about 1,000,000 to about 4,000,000 (page 5, lines 13+), nicotine-based drug, and co-solvent excipients (page 2,

lines 13+). Note that instant claim 7 recite a molecular weight of about 600,000 to about 1,000,000. Shear values were measured by using a 4.5 lb. rubber roller and allowed to equilibrate for 20 minutes. The specimen is mounted into the jaws of the Instron and pulled at a speed of 0.5 cm/min. and the peak load required to shear and separate the laminate is recorded in kg (page 8, lines 14+, see also table C2), It is the position of the Examiner that since the ranges of the molecular weight of the acrylic polymers overlap at the 1,000,000 value then it is expected that the shear resistance values should be overlapping. With regard to instant claim 5, Pfister discloses that the liquids are allowed to evaporate in room temperature (see examples A and B), which makes the composition substantially free of water and solvents. Pfister also discloses a pressure sensitive adhesive sandwiched between a backing substrate and a release liner (figure 1), and the delivery device is a matrix-type for a bioactive agent or drug in place within a transdermal patch (see figure 2) having the sufficient tack and shear to remain in place under conditions of use. Tack, peel, and adhesion values are disclosed (page 7, lines 40+). The methods recited in instant claims 17, and 21 is a conventional method comprising mixing polymer(s), drug(s) and solvent(s), forming a matrix then evaporating the solvent. The method is disclosed in example A, and B.

Because the same compounds have same properties, the recitation of “pressure-sensitive adhesive polymer having a shear resistance which is greater than or equal to 50 hours at 8 pounds per square inch and 720 Fahrenheit.” Is an inherent property to the same compounds of the preparation disclosed by Pfister.

***Conclusion: Claims 1-5, 7, 8, 10, 12, 14-22 are anticipated by Pfister.***

***Claim Rejections - 35 USC § 103***

4. The following is a quotation of 35 U.S.C. 103(a) which forms the basis for all obviousness rejections set forth in this Office action:

> (a) A patent may not be obtained though the invention is not identically disclosed or described as set forth in section 102 of this title, if the differences between the subject matter sought to be patented and the prior art are such that the subject matter as a whole would have been obvious at the time the invention was made to a person having ordinary skill in the art to which said subject matter pertains. Patentability shall not be negatived by the manner in which the invention was made.

This application currently names joint inventors. In considering patentability of the claims under 35 U.S.C. 103(a), the examiner presumes that the subject matter of the various claims was commonly owned at the time any inventions covered therein were made absent any evidence to the contrary. Applicant is advised of the obligation under 37 CFR 1.56 to point out the inventor and invention dates of each claim that was not commonly owned at the time a later invention was made in order for the examiner to consider the applicability of 35 U.S.C. 103(c) and potential 35 U.S.C. 102(e), (f) or (g) prior art under 35 U.S.C. 103(a).

Claims 1-23 are rejected under 35 U.S.C. 103(a) as being unpatentable over Pfister et al. EP 0524776 in view of Lee et al US 5284660 and further in view of Horstman et al. US 5230898 (Horstman).

Pfister has been discussed above. Pfister did not disclose the percentage of the drug used.

Lee teaches a device suitable for transdermal administration has a backing layer, which is not permeable to the agent delivered (col. 4, lines 10+). The delivered drug can be nicotine (col. 7, line 23); the amount of the drug is 40% of the dry composition (example 1, claims 13, 14, 19, and 20). In addition, it is noted that adjusting a specific transdermal dose of a drug is within a skilled artisan according to the condition it will be used for among many other factors while choosing between the different kinds of polymers recognized in the art to build a release-profile is also within the skills of an artisan unless documented by unexpected data results. Accordingly, it would have been obvious to one skilled in the art at the time the invention was made to combine the knowledge of Pfister with the dosage disclosed by Lee, the motive would

be the disclosure of Pfister that his invention provide a transdermal pressure sensitive with having the sufficient tack and shear to remain in place under conditions of use.

None of the references teach amphetamine in the transdermal delivery system.

Horstman teaches a transdermal therapeutic system exhibiting an increased active substance flow and process for the production, the system includes a layer serving as drug-reservoir, pressure-sensitive adhesive (col. 1, line 24). This layer comprises amphetamine (claim 6).

Accordingly, it would have been obvious to one of ordinary skill in the art at the time the invention was made to include amphetamine in the pressure-sensitive adhesive transdermal delivery system since the two inventions are in the same field and because the prior art suggested and achieved acceptable results in comprising amphetamine in the said system. The skilled artisan would have expectations of success since amphetamine has previously been included in a transdermal delivery systems successfully.

***Response to Arguments***

***1.*** Applicant's arguments filed 3/18/2008 have been fully considered but they are not persuasive.

***Claim Rejections - 35 USC § 112***

- Applicant argues that: “processing temperatures” are the temperatures at which the transdermal compositions are processed and that this is sufficient to render the claim clear. Further "Equal to or greater than the normal boiling points of the at least one low molecule weight drug " is clear and definite as written.

To respond: definiteness of claim language is to ensure that the scope of the claims is clear so the public is informed of the boundaries of what constitutes infringement of the patent and to provide a clear measure of what applicants regard as their invention. It is noted that the scope

of the claims cannot be determined since Applicant compares to properties of materials that are not recited in the claims such as the active agent and/or the adhesive polymers. In addition using “below processing temperature” or “equal to or greater than the boiling points of the at least one low molecular weight drug”. This adds to indefiniteness of the claim since Applicant compares to an unknown values that are for properties of an unknown material. Accordingly, the claims are not clear of what it include or exclude.

***Claim Rejections - 35 USC § 102***

***WO 93/00058 to Miranda et al.***

Applicant argues that: Miranda fails to disclose a system comprising a “high shear resistant acrylic-based pressure sensitive adhesive polymer having a shear resistance which is greater than or equal to 50 hours at 8 pounds per square inch and 72° F as claimed. The Office Action does not explain with sufficient rationale how Miranda inherently provides this teaching, as required for a rejection based on inherency.

**To respond**: A compound and its properties are not separable, the prior art clearly used the same polymers in the same invention (transdermal composition). Miranda describes an acrylic polymer which is in a preferred embodiment, the multiple polymer adhesive system that comprises a blend of an acrylic shear-resistant pressure-sensitive adhesive and a silicone pressure-sensitive adhesive (page 5). It is noted that a compound and its properties are not separable, the prior art clearly administers same ingredient (acrylic shear-resistant pressure-sensitive adhesive) in the same delivery form (transdermal) to same patients (in need for transdermal drug delivery systems). It is not necessarily that the prior art recognizes each and every advantage that a compound can accrue from the use of the particular ingredient. Prior art administers to the same patient population therefore there’s no invention in the recognition of these properties.

Applicant argues that: Miranda et al. does not anticipate the claimed invention because it does not disclose a transdermal drug delivery system comprising a blend of a) polymers; b) one or more drugs at least one of which is a low molecular weight. The office action fails to identify any particular polymer described as “high shear resistant acrylic based pressure-sensitive adhesive polymer”.

**To respond**: Miranda uses the same drug recited in the instant claims “nicotine”, and the same blend of polymers recited in the instant claims “polyacrylate and polysiloxane” to achieve the same result of having a transdermal drug delivery system. The reference does not have to describe the ingredients of the composition in the same words which Applicant uses.

Applicant argues that: claims 2-18 recite that the pressure-sensitive adhesive transdermal drug delivery system includes one or more high shear resistant acrylic-based polymers having a shear resistance which is greater than or equal to 50 hours at 8 pounds per square inch and 720 Fahrenheit. Claims 19-21 recite that the pressure-sensitive adhesive transdermal drug delivery system includes one or one or more high shear resistant acrylic-based polymers having a shear resistance which is greater than or equal to 50 hours at 4 pounds per square inch and 720 Fahrenheit. The '058 application does not describe compositions comprising such polymers.

**To respond**: since the prior art used the same polymers, the properties disclosed in the instant claims and not disclosed in the prior art are inherent.

Applicant argues that: Miranda application discloses compositions which include acrylic-based polymers such as Duro-Tak 80-1194, Duro-Tak 80-11196, and Duro-Tak 80-1197. However, none of these acrylic based polymers has a shear resistance that is greater than or equal to 50 hours at 4 pounds per square inch and 72° Fahrenheit, as set forth in claims 19-21, or greater

than or equal to 50 hours at 8 pounds per square inch and 720 Fahrenheit as set forth in claims 2-18. Thus, the '058 application does not anticipate claims 2-21.

**To respond**: Applicant is contradicting his own disclosures. Parent patent US 6,316,022 to Mantelle et al. (same inventive entity), discloses an invention, wherein a preferred embodiment, the high shear resistant polymer has a shear resistance which is .gtoreq. 50 hours at 4 pounds per square inch (psi) and 72º F, more preferably gtoreq.100 hours at 4 psi and 72º F, even more preferably gtoreq.100 hours at 8 psi and 72º F (col. 3, lines 52+). The polymers used in the 6,316,022 invention include the polyacrylate adhesives sold under the trademarks Duro-Tak 80-1194, 80-1196, 80-1197, 87-2287, 87-2516 and 87-2852 by National Starch and Chemical Corporation, Bridgewater, New Jersey. Other suitable acrylic adhesives are those sold under the trademarks Gelva-Multipolymer Solution GMS 737, 788, 1151 and 1430 (Monsanto; St. Louis, Mo.) (col. 8, lines 31+). Accordingly, Applicant used the same trademarks of polymers used by Miranda in his patent 6,316,022 and disclosed that the shear resistance of these polymers is .gtoreq. 50 hours at 4 pounds per square inch (psi) and 72º Fahrenheit, more preferably. gtoreq.100 hours at 4 psi and 72º F, even more preferably .gtoreq.100 hours at 8 psi and 72º F. patent 6316022, used Duro-Tak 87-2194 in all examples (examples 1-37) to ensure the properties recited in the instant claims and the instant disclosure used the same polymer in all examples (examples 1-37). (See patent 6316022 as an evidence for the position of the Examiner)

**EP 0524776 to Pfister et al.**

Applicant argues that: Pfister does not anticipate the instant claims comprising one or more polymers of high shear resistant acrylic-based pressure-sensitive adhesive polymer and a therapeutically effective amount of one or more drugs of a low molecular weight that is liquid at room temperatures as set forth in instant claim 1.

**To respond**: Pfister teaches a blend of polymers are used in the invention like siloxane polymers (page 3, line 10+), and acrylic acid polymers of high shear resistance (page 5, lines 13+), and nicotine-based drug, and co-solvent excipients (page 2, lines 13+)

Applicant argues that: EP '776 teaches the use of a "carbomer" in its silicone-based pressure sensitive adhesive, the "carbomer" is not a "high shear resistant acrylic-based pressure sensitive adhesive polymer," as recited in claim 1. Instead, the carbomer is used as a "cohesive strengthening agent" (e.g., a filler) and is dispersed in the silicone pressure-sensitive adhesive to increase cohesive strength. See EP '776, page 5, lines 29-30.

**To respond**: the carbomer used is a polyacrylic acid, which is an acrylic-based polymer. In addition, Pfister teaches that the desirable values of shear range between 15-25 kg. As shown in Table C2, values ranged from 18.0 (+/- 0.8) to 23.9 (+/- 0.0) kg which is within the range of the instant claims. Finally, Pfister comprised an acrylic-based polymer to achieve the same goal desired by Applicant; the resulting shear resistance is inherent.

Applicant argues that: The Office Action further argues that "Table C2" allegedly provides evidence of inherency of the recited shear resistance because the values in Table C2 are allegedly "within the range of the instant claims." However, this is a misrepresentation of Table C2. Page 14 of Pfister describes the shear of the entire adhesive composition.

**To respond:** even if the shear-resistance includes the whole adhesive composition, it is the position of the Examiner that since Pfister discloses acrylic acid polymers of high shear resistance that has molecular weights from about 1,000,000 to about 4,000,000 (page 5, lines 13+) this amount is overlapping with the instant claim 7, then the shear-resistance is expected to overlap.

***Claim Rejections - 35 USC § 103***

Applicant argues that: Pfister does not teach or suggest the invention recited in the independent claims, because neither Lee nor Horstman remedy this deficiency, the combination of EP '776 and Lee does not render the claimed invention obvious.

**To respond:** Applicant contends that Lee does not remedy the deficiency in Pfister, however, Applicant does not explain his position regarding the secondary references.

***Conclusion***

1. **THIS ACTION IS MADE FINAL.** Applicant is reminded of the extension of time policy as set forth in 37 CFR 1.136(a).

A shortened statutory period for reply to this final action is set to expire THREE MONTHS from the mailing date of this action. In the event a first reply is filed within TWO MONTHS of the mailing date of this final action and the advisory action is not mailed until after the end of the THREE-MONTH shortened statutory period, then the shortened statutory period will expire on the date the advisory action is mailed, and any extension fee pursuant to 37 CFR 1.136(a) will be calculated from the mailing date of the advisory action. In no event, however, will the statutory period for reply expire later than SIX MONTHS from the mailing date of this final action.

***Correspondence***

Any inquiry concerning this communication or earlier communications from the examiner should be directed to NABILA G. EBRAHIM whose telephone number is (571)272-8151. The examiner can normally be reached on 8:00AM-5:00PM.

If attempts to reach the examiner by telephone are unsuccessful, the examiner's supervisor, Michael Hartley can be reached on 571-272-0616. The fax phone number for the organization where this application or proceeding is assigned is 571-273-8300.

Information regarding the status of an application may be obtained from the Patent Application Information Retrieval (PAIR) system. Status information for published applications may be obtained from either Private PAIR or Public PAIR. Status information for unpublished applications is available through Private PAIR only. For more information about the PAIR system, see http://pair-direct.uspto.gov. Should you have questions on access to the Private PAIR system, contact the Electronic Business Center (EBC) at 866-217-9197 (toll-free). If you would like assistance from a USPTO Customer Service Representative or access to the automated information system, call 800-786-9199 (IN USA OR CANADA) or 571-272-1000.

/Nabila G Ebrahim/
Examiner, Art Unit 1618

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